IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re patent application of:	)	Before the Examiner
	)	J. L. Cumberledge
J. Stewart Young et al.	)	
	)	
Serial No. 10/695,067	)	Group Art Unit 3733
	)	
Filed: October 28, 2003	)	
	)	
MULTI-AXIAL CROSS-LINK CONNECTOR SYSTEM FOR SPINAL IMPLANTS	)	

DECLARATION UNDER 37 C.F.R. § 1.132

I, Stewart Young, declare as follows:

1. I am over 18 years of age, and am otherwise competent to make this Declaration. Unless otherwise stated, I have actual knowledge of all the facts stated in this Declaration.

2. I am an engineer employed by Medtronic Spinal & Biologics, Inc. ("Medtronic Spinal"), a developer and manufacturer of orthopedic devices used in spinal surgery headquartered in Memphis, Tennessee. My current job title is Senior R&D Manager, and I have been in that position for the last 2 years of the 16 years I have been employed by Medtronic Spinal. I have a bachelor's degree in mechanical engineering from the University of Memphis, in addition to 14 years experience in the orthopedic spinal implant field. In my capacity as an engineer, I have been a named inventor in several patents, including U.S. Patent No. 6,660,004. Accordingly, I believe I am a person of at least ordinary skill regarding spinal implant technology, including rod-linking devices.

3. This Declaration is being submitted to provide evidence to rebut allegations of obviousness made in connection with this application. I have reviewed the claims that are pending in this application, and I understand that they have been rejected as allegedly anticipated by U.S.

Patent No. 5,669,910 to Korhonen (the "Korhonen Reference"), or obvious over the Korhonen Reference itself or in combination with other references. I have reviewed the Korhonen Reference in making this Declaration.

4. Claim 1 recites an interconnection element including a first body having an aperture and a stud extending from the body, and item 16 in the specification and drawings is an example of that language. Claim 1 also recites a first rod connector that has a shaft terminating in a rod-engaging portion and a projection extending laterally from the shaft, with both the shaft and the projection received in the body aperture of the interconnection element. An example of that language is item 12 in the specification and drawings. Claim 1 also recites a second rod connector that has its own shaft that carries a body with an aperture, and the interconnection element's stud is received in that aperture. An example of that language is seen in item 14.

5. As one of at least ordinary skill in this art, my understanding of the Korhonen Reference is as follows. Items 18 and 28 connect to separate rods, with one rod fitting through hole 20 in a block portion of item 18, and the other rod fitting through hole 32 in a block portion of item 28. Item 18 has a rod 24 that is attached to its block portion and extends some length from it. Item 24a (Figure 4) is disclosed in the specification to be a part of rod 24, or stated differently, items 24 and 24a are actually the same piece. Item 28 has a slot portion 29 attached to its block portion for receiving part of rod 24/24a. A cap 30 fits over a part of rod 24/24a and slides onto the slot portion of item 28. A set screw 41 is threaded into the cap and presses rod 24/24a in the slot against item 28 to lock the four parts together.

6. Based on my understanding of Korhonen and of the terminology used in this art, the only items that could correspond to "rod connectors" are items 18 and 28, because they are the items that link to separate rods. Of the remaining parts shown in Korhonen, I do not see

anything that could correspond to the "interconnection element" recited in claim 1. The cap 30 does not have a stud. The only item in Korhonen that might be considered a "stud" by one of ordinary skill in this art is rod 24/24a, which is a part of item 18. To one of ordinary skill in this art, the cap 30 cannot be an interconnection element including a stud, because it does not include a stud. All it does is cover the part of the rod 24/24a of item 18 that is placed in the slot of item 28.

7. For purposes of this paragraph, I have assumed solely for the sake of argument that item 18 of Korhonen is a "first rod connector" and its cap 30 is an "interconnection element," as those items are recited in claim 1. In that case, I observe that the only part of item 18 that is received in cap 30 is the small portion of the rod 24/24a that fits in the slot (36) of item 28. No part of the block end of item 18 enters any part of the cap 30. I further observe from Figures 1 and 2 that no part of the block end of item 18 even abuts the cap 30, and I observe from Figure 5 that the teeth and grooves in the sides of the cap 30 and the item 28 mean that the cap 30 need not slide along or be adjacent to any part of the rod 24/24a other than that small end part that is in item 28. Consequently, if the block part of item 18 could be considered a "shaft" and rod 24/24a considered a "projection" according to claim 1, then as one of at least ordinary skill in this art, I cannot observe a shaft (block) and projection (rod 24/24a) received in an aperture of the cap 30 of Korhonen.

8. As one of at least ordinary skill in this art, it is not possible to understand one part of Korhonen's uniform cylindrical rod 24/24a as a "shaft" and another part of that same uniform cylindrical rod to be a "projection" that extends laterally from (i.e. to the side of) that shaft. The uniform cylindrical rod 24/24a as completely straight, with nothing extending off to the side of it.

9. Claim 44 recites a first rod connector that has a shaft terminating in a rod-engaging portion. That language is exemplified in item 12 in the specification and Figure 1. Claim 44 further recites a second rod connector that has its own shaft that carries a body, and that body has two apertures with particular orientations. An example of that language is seen in item 14 in Figure 1 of this application. Claim 44 also recites an insert for engaging the first rod connector's shaft, and the insert extends through one aperture of the second rod connector's body and in communication with the other aperture in the second rod connector's body. An example of that language is seen in item 16, shown in Figure 1.

10. Based on my understanding of the Korhonen reference, given above, one of ordinary skill in this art cannot find an insert that is configured to engage the shaft of the first rod connector, or an insert that extends through an aperture of the second rod connector. As already noted, items 18 and 28 of Korhonen are the only items that might be compared to the recited rod connectors. The only remaining item that could be compared to the claimed "insert" is the cap 30. Assuming solely for the sake of argument that item 18 of Korhonen is a "first rod connector" and rod 24/24a is its "shaft," I observe that the cap 30 does not and cannot engage rod 24/24a at all, as seen in Korhonen's Figure 3. Rather, the cap is placed over the end of item 28, and the rod 24/24a sits in the slot 36 of item 28, below the level of the surrounding walls in item 28. Further, the cap 30 does not extend through any aperture of item 28. It always remains external to item 28, as a cover for the slot 36. Conversely, assuming now solely for the sake of argument that Korhonen's item 28 is a "first rod connector," and its slotted part is a "shaft," I observe that the cap 30 does not extend through any aperture of item 18. It always remains external to the rod 24/24a, and it remains away from the block

portion of item 28, as seen in Figures 1 and 2 of Korhonen. Either way, as one of at least ordinary skill in this art I cannot find in Korhonen an insert as recited in claim 44.

11. Claim 8 recited that the shaft of the recited first rod connector was curved so as to be non-linear. I observe that all of the parts shown in Figures 1-5 of Korhonen are linear, including the rod 24/24a. One of ordinary skill in this art could not conclude that the rod 24/24a, or any other part of Korhonen's device, is non-linear.

12. Claim 11 recites that the shaft of the second rod connector can rotate about an axis defined by the stud to vary an angle defined by that shaft and the shaft of the first rod connector. I observe that Korhonen's items 18 and 28 can only define one angle—a 180 degree or straight angle. The interaction of the rod 24/24a and the slot 36 prevent them from defining any other angle. One of ordinary skill in the art could observe that item 18 could twist with respect to item 28, so that hole 20 is no longer parallel to hole 32, but the two parts 18 and 28 would still define a straight angle.

13. Claim 13 recites a washer carried by the stud and positioned between the stud and the aperture in the second rod connector in which the stud is received. Assuming solely for the sake of argument that the rod 24/24a is a "stud" and therefore the slot 36 is the aperture in which the stud is received, I do not observe anything between the rod 24/24a and the slot 36. I see no washer, as that term is understood in this art, of any kind in Korhonen.

14. Claim 18 recites that rotation of the first rod connector induces the recited projection to contact the body of the interconnection element and inhibit removal of the shaft of the first connector from the aperture in the interconnection element. Assuming solely for the sake of argument that item 18 of Korhonen is a "first rod connector" and its cap 30 is an "interconnection element," I observe that rotation of item 18 can only occur around the axis

of the rod 24/24a. Such rotation does not cause any part of item 18 to contact any part of the cap 30, as is evident from the cross-sectional view in Korhonen's Figure 3. Such rotation of a uniform cylinder could not result in any inhibition of removal of the rod 24/24a from within the cap 30.

15. Claim 31 recites that the rod-engaging portion of the first rod connector includes a hook. As one of at least ordinary skill in this art, the term "hook" has a well-understood meaning of an open-channeled or substantially J-shaped structure that allows anchoring to a rod, bone or other structure from the side, rather than from along the length of the connected item. Assuming solely for the sake of argument that Korhonen's item 18 is a "first rod connector," I observe that it is not a hook. I do not see a hook portrayed at all in Korhonen.

16. Claim 60 recites that the stud longitudinal axis is oblique to the longitudinal axis of the shaft of the recited first rod connector. As discussed above, I do not see a "stud" in the Korhonen reference as that term is used in the claims. The term "oblique" in this art, as in other areas, means non-parallel and non-perpendicular. If Korhonen were to be interpreted contrary to the understanding of one of ordinary skill in this art so that its rod 24/24a is both a shaft and a stud, I observe that all parts of rod 24/24a are parallel to each other, and therefore are not oblique.

17. Claim 61 recites that the shafts of the respective rod connectors are capable of pivoting with respect to each other between a substantially parallel position and a position defining an interior angle less than 180 degrees. As previously discussed, I observe that the Korhonen reference's items 18 and 28 can only form a straight angle. They are not capable of pivoting with respect to each other so as to be substantially parallel at one extreme or to define an internal angle of less than 180 degrees.

18. Claim 35 recites an insert included in addition to the features of claim 1, which is disposed within the aperture of the recited "interconnection element." Claim 36 recites that that insert with the aperture of the interconnection element define a ball and socket joint. As one of at least ordinary skill in this art, I do not see such an insert or ball and socket joint anywhere in the Korhonen reference. Further, claims 35 and 36 place the insert in the aperture of the recited "interconnection element." There is no room for an insert or ball-and-socket joint within cap 30 of Korhonen. Korhonen teaches sliding cap 30 over the slot in item 28, and so the inner space in cap 30 is occupied by a part of item 28. An insert in cap 30 would interfere with or prevent cap 30 from sliding onto item 28. Claim 54 recites an insert positioned within a body of an interconnection element. For the same reasons, Korhonen does not show that structure and cannot be modified to include it.

19. Claims 39 and 40 recite an insert or ball-and-socket joint formed in an aperture in the recited second rod connector. The close fit between rod 24/24a and the slot in item 28 (seen in Figure 3 of Korhonen) indicates that no such insert or joint can be placed in item 28. Even if an insert is in the slot in item 28, that close fit will prevent any use of the insert or ball-and-socket joint. The groove in the side of item 28 for part of cap 30 prevents widening the slot in item 28 for an insert or ball-and-socket joint. Widening the whole construct is inadvisable, as an important goal of spinal implants is to make them as small as possible. Claim 57 recites an insert positioned within a body of a second spinal rod connector. For the same reasons, Korhonen does not show that structure and cannot be modified to include it.

20. Claim 55 recites that the insert restricts movement of a shaft to inhibit disassembly. I have reviewed U.S. Patent No. 6,554,832 to Shluzas, which I understand was cited by the Examiner. Item 50 does not restrict movement of shaft 42, nor does it inhibit disassembly of

the Shluzas apparatus. It is clear to me and others of skill in this art that Shluzas' item 50 allows unlimited movement of its shaft 42 with respect to its items 50 and 30 until screw 58 locks the device.

21. Claim 13 and others recite a washer positioned between a stud on an interconnection element and the aperture of a second rod connector. I cannot find a washer in the Korhonen reference on any part of cap 30 or between any part of cap 30 and item 28 of Korhonen. Because cap 30 slides over part of item 30, with parts 46 of cap 30 in the side groove of item 28, a washer cannot be placed on cap 30 or between it and item 28. Placing a washer between cap 30 and item 28 (for example, against the end wall seen in Korhonen's Figure 4) will impede or prevent the sliding of cap 30 on item 28.

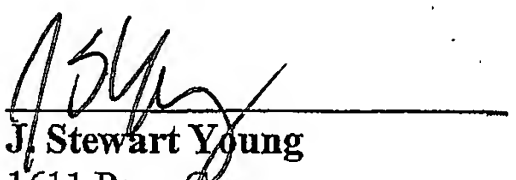
22. Claim 24 and others recite a washer carried by a stud of an interconnection member and positioned in a body of a second rod connector. I cannot find a washer in the Korhonen reference. As noted previously, there is no "stud" shown in Korhonen. Further, I understand Korhonen to show a close fit (Figure 3) between rod 24/24a and the slot in item 28, and that fit is necessary to allow the locking action of screw 41 to require minimal travel of rod 24/24a in that slot. It also presses practically all of the part of rod 24/24a in the slot against item 28. Korhonen, in my understanding, will not permit a washer to be placed on rod 24/24a inside item 28. The close fit will not permit such placement of a washer. Placing a washer in that location would require a larger slot, which goes against the close-fit teachings of Korhonen and is otherwise undesirable, as noted above.

23. Claim 37 recites a set of splines on a washer and another on the body of the second rod connector. Claim 38 recites that the washer has one or more recesses to contact a shaft of a first rod connector. I cannot find a washer in the Korhonen reference. The two sets of

splines indicate a surface-to-surface contact between the washer and the second rod connector body. No such washer can be placed in the Korhonen device, since placing a washer between cap 30 and item 28 (for example, against the end wall seen in Korhonen's Figure 4) blocks cap 30 from sliding onto item 28. Further, I do not see how a washer could contact both items 18 and 28 in Korhonen, because the reference must have cap 30 separating them. Without cap 30 separating those pieces, the Korhonen device will not work.

24. With my understanding of the Korhonen Reference, which I believe would be shared by others of skill in this art, it is my view that the Korhonen Reference does not show all features of any of the claims of the present patent application. Further, the addition to the Korhonen Reference of the features discussed above would not be obvious to one of skill in this art, at least because those features would defeat aspects of the Korhonen device or render it inoperable. Starting with the instruction of the Korhonen Reference, one of skill in this art is not directed suggested to make the additions discussed above.

25. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 28 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.



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